

CANNON BUILDING 861 SILVER LAKE BLVD., SUITE 203 DOVER, DELAWARE 19904-2467

STATE OF DELAWARE **DEPARTMENT OF STATE**

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DIVISION OF PROFESSIONAL REGULATION

CONTROLLED SUBSTANCE STATUTORY COMMITTEE REGULATORY SUB-COMMITTEE MINUTES FEBRUARY 9, 2011 GOVERNOR BACON BUILDING CONFERENCE ROOM DELAWARE CITY, DE 19706

Members present:

Howard Simon, R.Ph., Chair Bonnie Wallner, R.Ph. Alicia Kluger, R.Ph. David W. Dryden, R.Ph., Secretary

Members absent:

Michael Kremer, DMD Stephan Ruggles, PA-C Philip Kim, M.D. Patricia Murphy (DOJ)

Others Attending:

Jeanne Chiquoine

The meeting was called to order at 8:05 AM

Review of Controlled Substance Regulatory Issues

The Sub-Committee discussed regulatory issues including but not limited to Inventory Accountability CS Regulation 3.1.4, Verbal Prescriptions CS Regulation 4.2.2, Electronic Prescriptions CS Regulation 4.2.3, Electronic Signatures CS Regulation 4.4, 7 Day Prescription Validity CS Regulation 4.8.1, Identification CS Regulation 4.10.2 and Security CS Regulation 5.1.

The Sub-Committee reviewed the draft prepared by Ms. Davis-Oliva to address clarification of moving controlled substances in particular pharmacy transport situations (3.1.4); practitioner approval language for verbal prescriptions (4.2.2); to include electronic transmission (4.2.3/4.4); and security (specific inclusion of present requirements will be added. i.e. – floor to ceiling security, camera surveillance, back-up coverage) (5.1.1.4). The 7-day language of 4.8.1 will be amended to "such prescriptions may be dispensed up to a 100 dosage units or a 31-day supply whatever is greater". This language will address any confusion with limitation language. As per Dr. Kremer's recommendation at the last Committee meeting, the sub-committee members addressed identification language pertaining to concerns with the drop-off and pick-up identification requirements and other specific issues of concern under Regulation 4.10.2 (i.e. – nursing home drop off, mail order drop off, etc.)

The Sub-Committee reviewed the issues of interest submitted by Bruce DiVincenzo and Ray Hancock of ONDD.

- The Sub-Committee determined that the security inclusion requirements as amended above would be enforced for new and remodeled pharmacies. These standards would similarly be enforced when diversion for a particular established pharmacy warrants these inclusions.
- The Sub-Committee did not agree that identification should be obtained at the time of controlled substance prescription drop off.
- The issue of identification with drive thru pick up was discussed by the Sub-Committee. Mr. Hancock's e-mail was read (see attached). The Sub-Committee determined that an alert and newsletter should address this issue of identification.
- The Sub-Committee did not agree with any further additional members to the Committee.
 This issue has been addressed by the Committee and Secretary at previous hearings and meetings.

The draft amendment will be prepared and presented to the Controlled Substance Committee on February 23, 2011.

The meeting adjourned at 9:40 AM

Respectfully submitted,

David W. Dyd

David W. Dryden, R.Ph., J.D.

Secretary